UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Civil No. 0:13-CV-3003 (WMW/DTS)

United States of America, *ex rel.* Kipp Fesenmaier, Plaintiffs, v. The Cameron-Ehlen Group, Inc., d/b/a Precision Lens, and Paul Ehlen, Defendants.	)	**PLAINTIFFS' TRIAL BRIEF**

In accordance with the Court's Trial Notice and Final Pretrial Order (Doc. 737) dated July 20, 2022, the Plaintiffs in this case, the United States of America and Kipp Fesenmaier, submit their Trial Brief.

I. Trial Counsel.

The following attorneys will appear as trial counsel on behalf of Plaintiffs.

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II. Length of Trial.

Plaintiffs estimate that they will complete their case within 10-12 trial days, and trial can be completed in approximately four weeks, in addition to the jury selection days. Plaintiffs understand that the Court has allotted a maximum of six weeks for the introduction of evidence, and the final jury charge will occur no later than February 16, 2023.

III. Jurisdiction.

This Court has jurisdiction over this federal False Claims Act action pursuant to 28 U.S.C. §§ 1345 and 1331.

IV. Facts.

A. Summary

Defendants Precision Lens ("PL") and Paul Ehlen took ophthalmic surgeons on trips in order to obtain and retain their business, much of which was billed to Medicare. Plaintiffs allege that in the relevant time period, from 2006-2015, Defendant provided items of value in the form of private flights, frequent flier miles, tickets to exclusive

sporting events, and other items of value to induce surgeons to use PL-supplied products in cataract surgeries. Defendants provided those items to physicians for free or at a significant discount.

By paying these kickbacks, Defendants caused the submission of false claims to Medicare. The kickbacks include expensive trips involving private plane flights to the Masters Tournament, the Super Bowl, and a weekend trip for a Broadway show in New York City. Surgeons who received these kickbacks subsequently used PL-supplied products in cataract surgeries billed to Medicare. Defendants knew they could not provide such expensive gifts to customers.

B. Background

Defendant PL is a distributor of intraocular lenses ("IOLs"), viscoelastics and other products related to cataract surgeries. Mr. Paul Ehlen founded PL and has always been its CEO and majority owner, including from 2006-2015. Cataract surgeries are generally reimbursed by Medicare, a fact Defendants have long understood.

PL distributed for two of the three largest IOL manufacturers in the United States, Abbott Medical Optics, Inc. ("AMO")[1] and Bausch and Lomb ("B&L"). PL had a *de facto* exclusive distribution arrangement with AMO and B&L for Surgical Supplies within an eight-state area in the Midwest. In the rest of the country, PL distributed on a non-exclusive basis. PL sold "standard" and "premium" IOLs, but prioritized selling premium lenses as

[1] AMO has been acquired by Johnson and Johnson.

they generated approximately twice as much profit and the manufacturers pushed them to sell more.

For many years during the relevant time period ("RTP"), PL worked closely with Sightpath Medical ("Sightpath"), a company that offered mobile cataract surgery services. PL served as Sightpath's sales representative and also distributed products to Sightpath; PL referred to Sightpath as its largest customer. For most of the RTP, PL and Sightpath worked together to pursue relationships with various doctors.

PL maintained an account that it referred to as a "slush fund" or "secret fund." It was referred to as the secret fund because it was meant to be kept secret from others at Sightpath, including the private equity group that owned the company. PL and Sightpath's CEO, Jim Tiffany, used the secret fund in various ways to help PL, including taking physicians on trips when PL wanted to maintain a good relationship with them. This continued into 2012, when PL used the slush fund to send Sightpath's CEO, Jim Tiffany, hunting with Dr. Jitendra Swarup. Dr. Swarup had previously been a large customer of PL's and PL hoped that it could regain Dr. Swarup's business.

C. PL Provided Travel and Other Items of Value to Physicians to Induce Them to Use Products Distributed by PL

During the RTP, Defendants took physicians on luxury trips using two private planes, a larger jet known as the Bravo and a smaller plane known as the Baron.

Private flights included:

- Defendants flew Dr. Kurt Weir and his wife to the 2009 BCS National Championship Game in Miami, FL to watch Dr. Weir's favorite team;

- Defendants flew four physicians, including Dr. Weir and Dr. McKnight, to the 2011 Masters Golf Tournament in Augusta, GA, and gave them lodging, dinner and Masters tickets;
- In 2007, Defendants flew Dr. Patrick Riedel and Dr. David Hardten, two partners at Minnesota Eye Consultants, to Chicago, IL, and gave them a high-end meal and luxury hotel accommodations; and
- Defendants flew Dr. David West to the Super Bowl in 2011 to watch his favorite team play.

PL did not ask the physicians to pay anything for these trips, aside from asking the doctors to pay $500 each for the Masters trip.

D. Purpose of the Trips Was to Build Relationships and Generate Sales

PL's business model is based on using remuneration to build relationships with surgeon customers. Defendants regarded the ophthalmic surgeons as their principal customers. Defendants recognized that the surgeons usually decided what products to use in their surgeries. They therefore focused their sales efforts on the physicians.

PL's former Vice-President of Sales, Joel Gaslin, who went on numerous physician/PL trips, will testify that the trips were meant to build relationships and encourage the physicians to use PL-distributed products. Gaslin, who was involved in deciding trip attendees as early as 2000, indicated that PL used the trips to keep relationships with people or build relationships with people. PL indicated that "[a]n important key to selling anything is developing a relationship of trust with your

customer…Developing that relationship takes time and is best nurtured in both formal and casual settings…"

PL treated costs associated with physician trips as business expenses, and directly linked the trips to sales. In June 2008, Mr. Reichert indicated in company meeting minutes that Sutton Bay, one of Mr. Ehlen's private clubs, is expensive, so "if you don't have docs lined up or they drop out, then cancel your trip. Part of the benefit is in the asking." Mr. Reichert will testify that this directive came from Mr. Ehlen. Precision Lens sold SkyMiles to physicians on numerous occasions to facilitate the physicians taking flights at discounted rates. Mr. Reichert indicated in 2012 that PL would monitor the miles more closely in the future to make sure they are getting sufficient value from the miles when they sold them. Mr. Reichert will testify that Mr. Ehlen controlled the SkyMiles, and would provide them to physician customers who could benefit PL's business.

PL also assessed the value of charitable contributions when deciding which customers they support. When a PL executive suggested making a contribution to a foundation that was not affiliated with a large customer, Ehlen asked, "Why support them? What do they do for us?"

E. PL and Ehlen Knew That They Could Not Provide Items of Value

Mr. Ehlen will testify that he understood at all times between 2006 and 2015 that it was wrongful to subsidize physicians' travel. He admitted at his deposition that as of 2006, "I don't believe that I felt I could take [physicians] on trips and pay for them." He admitted that he knew throughout the RTP that it would be wrongful, inappropriate and maybe illegal to pay a portion of physicians' hunting costs. The company was specifically aware

in 2007 of a settlement in which a large local medical device company paid a large settlement for kickbacks related to entertainment practices and consulting contracts.

Plaintiffs will introduce evidence that in 2009, an industry trade group introduced a code of ethics called the AdvaMed Code. The Code set out prohibitions on a number of different practices related to physician entertainment. At a PL meeting in March 2009, the company's executives decided to change their practices going forward, cancelling hunting and fishing trips, doing away with providing sports tickets to customers, and halting the company's practices of providing extravagant meals for physicians and spouses. Consistent with the company's practice of connecting these items with sales, the company indicated that it would monitor to see if this change would have an effect on sales. Notwithstanding its plan in March 2009, PL continued the same conduct.

In June 2009, Precision Lens sought legal advice from outside counsel regarding prohibitions under the AKS. Among other things, counsel advised the company not to provide physician customers free travel for entertainment purposes or provide free travel to a spouse or guest "in any circumstance." After a 2008 trip with Mr. Ehlen, Dr. Swarup, and Mr. Tiffany, which was financed by the secret fund, Mr. Tiffany told Dr. Swarup, "You gotta go there. Hunting equal to White Lake, with country club amenities and a great wine cellar!" In September 2009, just a few months after PL executives discussed halting such trips, and after an outside lawyer provided the advice discussed above, Defendants used the secret fund for another Sutton Bay trip. This time, PL flew Dr. Richard Lindstrom and his son on a private plane to Sutton Bay, accompanied by Mr. Ehlen and Mr. Tiffany, just as Mr. Tiffany had suggested. Later in 2009, Defendants flew Dr. Lindstrom to hunt in

White Lake in 2009 on a private flight. Defendants also flew Dr. Richard DeChamplain to White Lake on that flight, along with his former partner Dr. Gerald Tiller, a guest of Dr. DeChamplain's that Defendants included at his request. There is no record of any of the doctors paying for the flight or the hunting.

PL sought to create annual trips with physicians. Dr. DeChamplain will testify that he went hunting in White Lake with PL every year from 2006-2015, and almost every year a core group including Dr. DeChamplain, Dr. Tiller, Dr. Lindstrom and Mr. Ehlen went on the trip. And every year Dr. DeChamplain took a flight to Minneapolis, generally with Dr. Tiller, and each time Mr. Ehlen's assistant booked that travel for them, along with a hotel for the night before the trip. Annually, both before and after Defendants received outside legal advice telling them not to take physicians on discounted trips, and under no circumstances to take their guests, Defendants flew Dr. DeChamplain and his guest Dr. Tiller from Minneapolis to White Lake on a private plane. The evidence will show that Defendants continued to take Dr. DeChamplain and Dr. Tiller without charging them, even after receiving the clarifying legal advice and specifically discussing that they would need to halt such trips.

F. The Kickbacks Enabled Defendants to Retain Customers, Gain Others, and Increase Volume

PL had lost Dr. DeChamplain as a customer in 2009 when AMO told PL that AMO would sell directly to Dr. DeChamplain. PL continued to offer him items of value, including the annual hunting trips and others. Dr. DeChamplain requested in 2011 that AMO let him buy PL-distributed lenses again, and AMO agreed to do so. In September

2011, Dr. DeChamplain committed to purchasing 10,200 AMO lenses from PL over the following three years.

In April 2011, Defendants flew Doctors Weir, McKnight, Timothy Cavanaugh, and Stephen Wiles on the Bravo to the Masters Golf tournament in Augusta, Georgia. Defendants also provided the physicians with lodging in a private home, tickets to the Masters, and a steak dinner. Although its records indicate that PL paid $19,632.20 for the flight alone, Defendants invoiced each physician only $500 for the entire trip. That amount was well below the fair market value of the trip. PL's internal documents indicate that beginning in 2011, the same year as the Masters trip, Dr. Weir's deluxe IOL purchases increased tenfold, from 31 to 312 deluxe B&L lenses. An independent sales representative who accompanied the four doctors on the Masters trip in April 2011 indicated that same month that he had moved two of the doctors back to PL products, and PL documents showed increases in their uses of premium lenses after the trip. In September 2011, Dr. McKnight requested that he be permitted to purchase his premium lenses from PL instead of directly from the manufacturer.

The kickbacks also permitted Defendants to retain customers. Defendants believed that one of the primary roles of their salespeople was to retain existing business. They were concerned about losing business to competitors, especially Alcon, or to the physicians buying directly from the manufacturers, as Dr. DeChamplain had. PL knew that if it lost too much business, the manufacturers could terminate their relationship with PL and sell directly to PL's physician customers. The evidence will demonstrate that the purpose of the kickbacks was focused to a large degree on strengthening relationships so doctors

would continue ordering products from PL and increase their orders of products that produced higher profits for PL.

Defendants intended that after the physicians received the items of value, they would use PL-distributed products in surgeries paid for by Medicare. Defendants have long understood that Medicare pays for most cataract surgeries. They understood that those surgeries included payments for both facility fees and professional fees. They knew that PL's surgical supplies, including IOLs, were reimbursed as a part of the facility fee payment, and understood that the physicians implanting those IOLs would be submitting bills to Medicare for their professional services.

V. Plaintiffs' Claims.

Plaintiffs bring two causes of action against Defendants under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, for false or fraudulent claims to Medicare premised on violations of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b). *See* Doc. 105, First and Second Claims for Relief. Specifically, Plaintiffs bring causes of action under Sections (a)(1)(A) and (a)(1)(B) of the FCA, which "imposes civil liability on any person who 'knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval' or 'knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.'" Doc. 152, Oct. 22, 2018 Order at 10, citing 31 U.S.C. § 3729(a)(1)(A), (B).

Plaintiffs intend to prove at trial that from 2006-2015, Defendants knowingly provided remuneration, in the form of private flights, frequent flier miles, tickets to exclusive sporting events, expensive meals, and other items of value, with at least one

purpose to induce surgeons to use PL-supplied products in cataract surgeries. Plaintiffs claim that by paying these kickbacks, Defendants knowingly caused the submission of false claims to Medicare and caused false records to be made or used.

A. The False Claims Act.

The FCA is "the Government's primary litigative tool for combating fraud." S. Rep. No. 99-345, 99th Cong., 2d Sess. 2, reprinted in 1986 U.S.C.C.A.N. 5266. When enacting the False Claims Act, "Congress wrote expansively, meaning 'to reach all types of fraud, without qualification, that might result in financial loss to the Government.'" *Cook Cnty., Ill. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) (quoting *United States v. Neifert-White Co*., 390 U.S. 228, 232 (1968)).

The elements of a § 3729(a)(1)(A) claim are: (1) the defendant presented or caused the presentment of a claim for payment to the United States, (2) the claim was false or fraudulent, and (3) the defendant knew the claim was false or fraudulent. Doc. 722, January 12, 2021 Order, at 4; *Olson v. Fairview Health Servs. of Minn.*, 831 F.3d 1063, 1070 (8th Cir. 2016). Likewise, the elements of a § 3729(a)(1)(B) claim are: (1) the defendant made or caused to me made or used a false record or statement; (2) the defendant knew the statement was false; (3) the statement was material; and (4) the statement made a claim for the government to pay money or forfeit money due. *United States ex rel. Benaissa v. Trinity Health*, 963 F.3d 733, 741 (8th Cir. 2020) citing *United States ex rel. Miller v. Weston Educ., Inc.*, 840 F.3d 494, 500 (8th Cir. 2016). Here, Plaintiffs allege Defendants are liable for causing a false claim to be presented, or a false record to be made or used.

1. False or Fraudulent Under the FCA.

Recently, the Eighth Circuit addressed FCA liability established solely through 42 U.S.C. § 1320a-7b(g), a 2010 amendment to the Anti-Kickback Statute. *United States ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828 (8th Cir. 2022). That amendment added new subsection (g), providing "a claim that includes items or services resulting from a violation" of the AKS "constitutes a false or fraudulent claim for purposes of [the FCA]." *Cairns* held that the "resulting from" language of the amendment requires application of but-for causality to establish a false or fraudulent claim. *Id.* at 835 (citing *Burrage v. United States*, 571 U.S. 204, 210-11, (2014)). As the Eighth Circuit made clear: "There are several ways to prove that a claim is 'false or fraudulent' under the False Claims Act." *Cairns*, 42 F.4th at 831 (citing 31 U.S.C. § 3729(a)(1) (emphasis added)). Only "[o]ne of them" is through the 2010 AKS amendment. *Id.*[2]

Here, Plaintiffs can prove FCA liability for all claims in the relevant time period, 2006-2015, without relying on the 2010 AKS amendment. Indeed, much of the conduct alleged to violate the AKS and FCA in this matter predates the 2010 amendment. Doc. 105, ¶ 6 ("The relevant time period ("RTP") for this Complaint is January 1, 2006 through December 31, 2015."). As such, Plaintiffs have always asserted that the claims at issue are false and fraudulent because they violated material terms of federal healthcare payment.

[2] The Court specified: "Our ruling today is narrow. We do not suggest that every case arising under the False Claims Act requires a showing of but-for causation." *Cairns,* 42 F.4th at 836-37 (emphasis added). Rather, it applies only "when a plaintiff seeks to establish falsity or fraud through the 2010 amendment". *Id*. (distinguishing that it was the government's "sole theory at trial").

For claims dated after its enactment on March 23, 2010, Plaintiffs also asserted supplemental FCA liability through the 2010 AKS amendment, but continued to maintain their original theory of falsity.

With the benefit of the guidance of the Eighth Circuit in *Cairns*, Plaintiffs seek to prove at trial one theory of FCA liability, independent of the 2010 AKS amendment, through the entire time frame. Plaintiffs believe that this will also prevent jury confusion from having two different standards of FCA liability – i.e., that of material falsity in the time frame 2006 – March 22, 2010 and that of falsity through the 2010 AKS amendment in the time frame March 23, 2010 – 2015. However, if the Court determines that this approach is not permissible, and requires falsity to be established in multiple ways in the 2010-2015 time frame (meaning, by both material falsity and through the *Cairns* interpretation of the 2010 AKS Amendment), Plaintiffs address the applicable standard under *Cairns* in section (d) below. Before doing so, Plaintiffs address FCA liability premised on material falsity.[3]

a. <u>FCA Liability Premised on Material Falsity.</u>

Plaintiffs intend to prove that the claims at issue are false or fraudulent because they violate material terms of Medicare reimbursement. Under the FCA, the "term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). As the Supreme Court explained in

[3] Pending further clarity on this issue, Plaintiffs have for now proposed jury instructions that address both theories of falsity, premised on both material falsity and based on the 2010 AKS Amendment.

Universal Health Servs., Inc. v. United States ex rel. Escobar, 579 U.S. 176 (2016), "materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'" 579 U.S. at 193 (citation omitted). Courts may analyze materiality from either the perspective of a "reasonable" person or the particular defendant. *Id.* at 193 ("[A] matter is material . . . (1) '[if] a reasonable [person] would attach importance to [it] in determining his choice of action in the transaction'; or (2) if the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter 'in determining his choice of action,' even though a reasonable person would not.") (citing Restatement (Second) of Torts § 538 (1977)). Material omissions and misrepresentations include violations that go to "core" or "basic" requirements, *id.* at 189-90; go to the "essence of the bargain," *id*. at 193 n.5 (citation omitted); are "substantial," *id.* at 194, or are similar to where the government took action in this or other cases when it had knowledge of the violations, *id.* at 193-94.

This precisely describes the materiality of the AKS requirements. By prohibiting the payment of kickbacks, the AKS ensures that the government pays only for conflict-free medical care that is provided in the best interests of the patient and that is not potentially affected by financial considerations. *See United States v. Patel*, 778 F.3d 607, 612 (7th Cir. 2015). "The Government does not get what it bargained for when a defendant is paid by [the Government] for services tainted by a kickback." *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011). "Kickbacks are designed to influence providers' independent medical judgment in a way that is fundamentally at odds

with the functioning of the system as a whole." *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 53 (D. Mass. 2011).

Accordingly, long before the AKS amendment,[4] courts routinely held that FCA claims premised on AKS violations are false or fraudulent because they seek payment for services that are not payable by Medicare because they violate a material condition of reimbursement. *United States v. Rogan*, 459 F. Supp. 2d 692,717, 724 (N.D. Ill. 2006) ("compliance with the [AKS] is a condition of payment"); *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1260 (11th Cir. 2005) (claims in violation of AKS are ineligible for payment and establish FCA liability because "compliance with the [AKS] is necessary for reimbursement under the Medicare program"); *United States ex rel. Nehls v. Omnicare, Inc. et al.*, No. 07-C-05777, 2013 U.S. Dist. LEXIS 102543, at *27, (N.D. Ill. July 23, 2013) ("compliance with the AKS…is a condition of reimbursement"); *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 565 F. Supp. 2d 153, 159 (D.D.C. 2008) ("Legion other cases have held violations of AKS...can be pursued under the FCA, since they would influence the Government's decision of whether to reimburse

[4] The AKS amendment has been generally viewed to have codified the materiality of AKS violations. *Guilfoile v. Shields,* 913 F.3d 178, 190 (1st Cir. 2019) (AKS amendment "obviat[es] the need for a plaintiff to plead materiality -- that is, to plead that compliance with the AKS was material to the government's decision to pay any specific claim."); *United States v. Biogen Idec Inc.,* Civil Action No. 1:12-cv-10601-IT, 2022 U.S. Dist. LEXIS 117512, at *10 (D. Mass. July 5, 2022) (amendment codifies the link between AKS violations and false claims); *United States ex rel. Goodman v. Arriva Med., LLC*, 471 F. Supp. 3d 830, 842 (M.D. Tenn. 2020) ("'false or fraudulent claim' is a term of art that now categorically includes claims resulting from an AKS violation, regardless of materiality to any payment decision").

Medicare claims."); *United States ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 616 (N.D. Ill. 2003) ("Compliance with the AKS is thus central to the reimbursement plan of Medicare."); *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 32 (D.D.C. 2003) ("Courts have found that kickback . . . violations affect the government's decision to pay.").

Over time, courts have used different terminology to reach these conclusions – i.e., material misrepresentation, false certification, implied certification – but the central reasoning is the same: A claim for medical care corrupted by an AKS violation is false because compliance with the AKS is a threshold and fundamental condition of payment by the government. *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 392 (1st Cir. 2011).

b. *Escobar* Material Omissions.

In *Escobar,* the Supreme Court confirmed that falsity can be demonstrated by material omissions. The Court held that "liability can attach when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement." *Escobar*, 579 U.S. at 181. The representations that can establish liability include "payment codes that correspond to specific … services" and "National Provider Identification [("NPI")] numbers corresponding to specific job titles" because they would lead "anyone" to "wrongly[] conclude" that those services and providers had complied with "core" Medicare requirements. *Id.* at 189. "By using payment and other codes that conveyed this information without disclosing [defendant's] many

violations of basic [ ] requirements…, [defendant's] claims constituted misrepresentations." *Id*. at 190.

Escobar's holding regarding material omissions has been routinely applied to FCA cases premised on violations of the AKS. *E.g., United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 817-18 (S.D.N.Y. 2017) (applying the *Escobar* "holistic" approach, the court "has no trouble concluding that compliance with the AKS is a 'material' condition of payment."), reversed on other grounds, 899 F.3d 163, 166 (2d Cir. 2018); *United States v. Am. at Home Healthcare & Nursing Servs.*, No. 14-cv-1098, 2017 U.S. Dist. LEXIS 94505 at *20-23 (N.D. Ill. June 20, 2017) (rejecting post-*Escobar* materiality challenge for AKS violations).

Thus, the claims at issue in this matter can be proven false or fraudulent based on material omissions and misrepresentations. *Escobar,* 579 U.S. at 181; *Hutcheson*, 647 F.3d at 388. Under this theory of liability, the cataract surgery claims were presented with specific billing codes as if they were eligible for payment, but without disclosing that the providers associated with the claim were illegally incentivized in violation of the AKS, a material term of payment of those claims. This encompasses both the facility fee and professional fee associated with cataract surgeries performed by physicians illegally incentivized to use products distributed by Precision Lens ("PL products") for use in cataract surgeries.

c. Materiality of Compliance with the AKS.

The serious nature of AKS compliance in the federal healthcare programs is beyond dispute. Congress enacted the AKS in 1972 as part of the Social Security Act to "include

as fraud such practices as kickbacks and bribes" within the penalty provisions applicable to Medicare, because they "contribute appreciably to the cost of the programs."[5] In 1977, Congress made AKS violations a felony and specified that the kickback prohibition extended broadly to the offer or payment of any remuneration, directly or indirectly, overtly or covertly, in cash or in kind.[6] The legislative history emphasized that the amendments were introduced to "give a clear, loud signal" and in "unmistakable tones" that Congress meant to "call a halt" to abuse of the Medicare funds with AKS violations.[7]

Ten years later, Congress strengthened the AKS again as part of the Medicare and Medicaid Protection Act of 1987. Pub. L. No. 100-93, 101 Stat. 680 (Aug. 18, 1987). Congress again sought "to improve the ability of the Secretary and the Inspector General of the Department of Health and Human Services to protect [the] Medicare [and] Medicaid ... programs from fraud and abuse ...." S. Rep. 100-109, 100th Cong., 1st Sess. at 1, *reprinted in* 1987 U.S.C.C.A.N. 682, 682.

Congress amended the AKS again in 2010, as part of the Patient Protection and Affordable Care Act ("PPACA"). While *Cairns* addressed the meaning of the text of the amendment for the purpose of establishing falsity, it did not address its relevance for the

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[5] S. Rep. No. 92-1230, 92d Congress, 2d Sess. (1972) at 43, 208. *See also* Pub. L. No. 92-603, 86 Stat. 1329, 1419-20 (Oct. 30, 1972); H.R. Rep. No.95-393, 95th Cong., 1st Sess. (1977) at 52-53, *reprinted in* 1977 U.S.C.C.A.N. 3039, 3055; S. Rep. No. 95-453, 95th Cong., 1st Sess. (1977) at 11.

[6] P.L. 95-142, 91 Stat. 1175 (Oct. 25, 1977), *codified at* 42 U.S.C. § 1320a-7b.

[7] 123 Cong. Rec. 31767 (Sept. 30, 1977) (Remarks of Sen. Talmadge) (emphasis supplied).

purpose of establishing materiality under *Escobar.* In the context of materiality, the 2010 Amendment reflects that Congress has consistently strengthened the AKS over time, in line with the findings over many decades that kickbacks are a serious harm to government healthcare programs. As described by co-sponsor Senator Patrick Leahy, the amendment to the AKS was enacted

> to ensure that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil action under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves. All too often, health care providers secure business by paying illegal kickbacks, which needlessly increase health care risks and costs. This change will help ensure that the government is able to recoup from wrongdoers the losses caused by false health care fraud claims.

155 Cong. Rec. S10854 (Oct. 28, 2009). As further stated by amendment sponsor Senator Ted Kaufman, the amendment was intended to remove obstacles to DOJ's "success both prosecuting illegal kickbacks and pursuing False Claims Act matters based on underlying violations of the Anti-Kickback Statute." 155 Cong. Rec. S10853 (October 28, 2009).

The "clear, loud signal" sent by Congress has also been consistently echoed by the Centers for Medicare and Medicaid Services ("CMS"). CMS has long defined kickbacks as a fraud on federal health care programs. Publication 13, Medicare Intermediary Manual, Part 2 at § 2060.5 (1980), and Part 4 at § 4100.2, Definitions (1989).[8] As explained in the *Final Compliance Program Guidance for Pharmaceutical Manufacturers*,

> Manufacturers, providers, and suppliers of health care products and services frequently cultivate relationships with physicians in a position to

[8] *Accord* Medicare Financial Management Manual, Ch. 8, § 140, Fraud and Abuse (*see also* sections 30 and 40, Field and In-House Audits) (internet-only manuals available at http://www.cms.gov/Manuals/).

> generate business for them through a variety of practices, including gifts, entertainment, and personal services compensation arrangements. These activities have a high potential for fraud and abuse and, historically, have generated a substantial number of anti-kickback convictions.

68 Fed. Reg. 23731, 23737 (May 5, 2003).[9]

Nearly 20 years ago, in 2001, CMS amended the Medicare provider agreement to require every provider to certify its understanding that "payment of a claim by Medicare or other federal healthcare programs is conditioned on the *claim and the underlying transaction* complying with such laws, regulations and program instructions (including the anti-kickback statute and the Stark law) . . . ." *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc.*, 238 F. Supp. 2d 258, 264 (D.D.C. 2002); *see also* Form CMS-855A; Form CMS-855B (effective 2001) (emphasis added).[10] The provider agreement makes plain that the United States requires that it not be billed for any items or services

[9] Available at http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf; *see also* 1999 Office of Inspector General ("OIG") *Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics, and Supply Industry*, 64 Fed. Reg. 36368 (July 6, 1999) (suppliers "will not submit or cause to be submitted claims…for patients" who were referred …pursuant to financial arrangements that were designed to induce such referrals in violation of the AKS; nor should it provide "gifts, free services, other incentives or things of value to….potential referral sources for the purpose of inducing referrals in violation of the [AKS]"), available at https://oig.hhs.gov/documents/compliance-guidance/804/frdme.pdf.

[10] Current Form CMS 855s are available at https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-List; the current Form CMS 855i is available at https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855i.pdf; the Form 855b (for providers and suppliers) used in 2001 and referenced in *Pogue* is available at http://www.primarybilling.com/pdf/cms855b.pdf,
or
https://web.archive.org/web/20020918001424/http:/cms.hhs.gov/providers/enrollment/forms/

related to the offer or payment of remuneration. *See, e.g., Hutcheson*, 647 F.3d 377 at 392-94 (Medicare claims were ineligible for payment because a kickback affected the underlying transaction with the provider performing the Medicare service); *United States ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp. 3d 323, 336-37 (S.D.N.Y. 2014) ("failure to comply with the AKS in completing the 'underlying transaction'" renders the claim false). Here, the underlying transaction at issue is the provision of kickbacks to physicians to induce them to use PL products in cataract surgeries, in violation of the AKS.

d. Falsity Established Through the AKS Amendment Under *Cairns.*

As discussed above, unlike the Eighth Circuit's statement in *Cairns,* Plaintiffs do not rely solely on the 2010 AKS amendment to establish falsity for underlying AKS violations. With the benefit of the Eighth Circuit's decision, Plaintiffs seek to establish falsity through material omissions so that the jury is not confused with different standards in the pre- and post-2010 time frames. As the Eighth Circuit made clear, the 2010 amendment is only one of the "several ways" to prove that a claim is 'false or fraudulent' under the False Claims Act." *Cairns*, 42 F.4th at 831.

If the Court determines that falsity for claims dated after March 23, 2010 should alternatively be established through the 2010 AKS Amendment, Plaintiffs would seek to establish falsity in that time frame through both material falsity and the 2010 AKS Amendment (as independent theories of falsity). As the Court is aware, and addressed at length in the summary judgment order, the 2010 AKS amendment added new subsection (g), providing "a claim that includes items or services resulting from a violation" of the AKS "constitutes a false or fraudulent claim for purposes of [the FCA]." *Cairns* held that

the "resulting from" language of the amendment "creates a but-for causal requirement between an anti-kickback violation and the 'items or services' included in the claim." *Cairns,* 42 F.4th at 834.

The court in *Cairns* remanded for a new trial for the district court to issue a but-for causation instruction, given that the "government's sole theory at trial hinged on the 2010 amendment." *Cairns,* 42 F. 4th at 837.[11] The Eighth Circuit specified that "when a plaintiff seeks to establish falsity or fraud through the 2010 amendment, it must prove that a defendant would not have included particular 'items or services' but for the illegal kickbacks." *Id.* at 836 (emphasis supplied). In *Cairns,* the defendant referenced was a neurosurgeon, who submitted the claims and received the kickbacks. *Id.* at 831-832.[12] The panel did not further flesh out the jury instruction, except to make clear that "textbook" but-for causation principles should be applied. *Id.* at 835, citing *Burrage*, 571 U.S. at 211.

As applied to the facts in this matter, but-for causation means that false or fraudulent claims are established when Defendants' kickbacks were at least one but-for cause of claims for cataract surgeries that included the implanting of PL-distributed lenses by illegally incentivized physicians. This comports with the textbook definition of but-for causation under Supreme Court and Eighth Circuit precedent.

[11] The court found "the government presented enough evidence on the 'essential elements' of the claim, including causation, to receive a new trial." 42 F.4th at 837 n.3.

[12] The neurosurgeon Fonn and his medical practice received kickbacks from his fiancé's medical supply company, who was also a defendant.

It is well-settled that but-for causation includes events that "have multiple but-for causes." *Bostock v. Clayton Cty.*, 140 S. Ct. 1731, 1739-40 (2020). As explained in *Bostock,* but-for causation "can be a sweeping standard." *Id.*[13] "[T]raditional but-for causation standard means a defendant cannot avoid liability just by citing some *other* factor that contributed to its challenged employment decision." *Id. Bostock* points out that had Congress intended the prohibited conduct to be the main cause of the challenged result, the statute at issue could have specified with language like "solely" or "primarily because of." *Id*. Like the Title VII provisions at issue in *Bostock,* the FCA contains no such language.

The Eighth Circuit, too, has addressed but-for causation in multiple contexts. In *United States v. Cathey*, the Court addressed but-for causation in the context of the Contolled Substances Act ("CSA") and made clear that it does not require drugs to be the "*sole* cause" of the injury. 997 F.3d 827, 833-34 (8th Cir. 2021) (emphasis in original)[14] Rather, they "needed only to be one link in the chain of events necessary for the injury or death to occur." *Id.* In *Cincinnati Ins. Co. v. Rymer Co., LLC*, the Court held that the event at issue (a tornado) properly sat in the causal chain under traditional but-for principles, even though the harm (enforcement of a building ordinance to require roof replacement) was also caused by another pre-existing condition (the prior water-soaked condition of the

[13] But-for causation is a broad, rather than a vigorous, standard. *Ford Motor Co. v. Mont. Eighth Judicial Dist. Court*, 141 S. Ct. 1017, 1034 (2021) (Gorsuch, J., concurrence) ("but-for causation test isn't the most demanding. At a high level of abstraction, one might say any event in the world would not have happened 'but for' events far and long removed."); *Paroline v. United States*, 572 U.S. 434, 450 (2014) (sometimes that showing could be made with little difficulty).

[14] *Cathey* was also decided after the Supreme Court addressed the CSA in *Burrage*.

roof). 41 F.4th 1026, 1029-30 (8th Cir. 2022). Moreover, the Eighth Circuit's pattern instructions for Title VII, Age Discrimination in Employment Act ("ADEA"), and 42 U.S.C. § 1881 matters reflect *Bostock*'s holdings regarding multiple but-for causes.

2. Knowing Conduct Under the FCA.

Under the FCA, "knowingly" means the individual: "(i) has actual knowledge of the information; (ii) "acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information. . . ." 31 U.S.C. § 3729(b)(1)(A). Critically, under the FCA, "no proof of specific intent to defraud is required." 31 U.S.C. § 3729(b)(1)(B);

3. Causing Presentment of Claims.

"Under the FCA, a defendant may be liable either for directly submitting a false claim or for *causing* a false claim to be submitted." Doc. 722 at 28-29 (emphasis in original), citing 31 U.S.C. § 3729(a)(1)(A) (imposing liability on anyone who "causes to be presented" a false claim) and *Hutcheson*, 647 F.3d at 390 ("The Supreme Court has long held that a non-submitting entity may be liable under the FCA for knowingly causing a submitting entity to submit a false or fraudulent claim . . . ."). This Court has held, consistent with multiple circuit courts, that a proximate causation standard applies to "causing" false claims to be submitted. *Id.*, citing, *e.g., Ruckh v. Salus Rehab., LLC*, 963 F.3d 1089, 1106-07 (11th Cir. 2020); *United States ex rel. Sikkenga v. Regence BlueCross BlueShield of Utah*, 472 F.3d 702, 714-15 (10th Cir. 2006), *abrogated on other grounds by Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 139 S. Ct. 1507, 203 L. Ed. 2d 791 (2019).

"Under this analysis, a defendant's conduct may be found to have caused the submission of a claim for Medicare reimbursement if the conduct was (1) a substantial factor in inducing providers to submit claims for reimbursement, and (2) if the submission of claims for reimbursement was reasonably foreseeable or anticipated as a natural consequence of defendants' conduct." *Id.*, quoting *Ruckh*, 963 F.3d at 1107 (internal quotation marks omitted).

This Court's ruling on FCA causation is unaffected by *Cairns.* As previously addressed, the Eighth Circuit's decision was specifically limited to interpretation of the 2010 AKS amendment. *Cairns,* 42 F.4th at 836-37. Its holding on but-for causality relates only to the standard for establishing falsity through the amendment, § 1320a-7b(g), and is not FCA causation. This is consistent with the Court's summary judgment opinion, which distinguishes FCA causation from AKS causation, i.e., proving false or fraudulent claims through the 2010 amendment. Doc. 722 at 25, 28.

B. <u>The Anti-Kickback Statute.</u>

This Court has held: "Four elements comprise a violation of the AKS: (1) the defendant acted knowingly and willfully; (2) the defendant offered or paid any remuneration—including a kickback, bribe, or rebate—directly or indirectly, overtly or covertly, in cash or in kind, to any person; (3) the remuneration was offered or paid to induce such person to purchase, lease, order—or arrange for or recommend purchasing, leasing, or ordering—any good, facility, service, or item, or to refer an individual to a person for the furnishing of any item or service; and (4) such good, facility, service, or item was one for which payment may be made in whole or in part under a federal healthcare

program." Doc. 722 at 4-5, citing 42 U.S.C. § 1320a-7b(b)(2); *United States v. Nerey*, 877 F.3d 956, 968 (11th Cir. 2017); *United States v. St. Junius*, 739 F.3d 193, 210 n.18 (5th Cir. 2013). The Court held that there "is no dispute that the fourth element of an AKS violation is satisfied here—namely, that the products Defendants sold to physicians are goods for which payment may be made under Medicare." *Id.* Thus, the remaining three elements are discussed below.

1. Knowing and Willful Conduct.

This Court has held that the "knowingly and willfully" element of an AKS violation requires a defendant to know that the conduct at issue was wrongful." Doc. 722 at 5, citing *United States v. Jain*, 93 F.3d 436, 440-41 (8th Cir. 1996). "A defendant need not have acted with the specific intent to violate the AKS." *Id.* "In both civil and criminal contexts, 'circumstantial evidence can demonstrate willfulness' and is 'just as probative as direct evidence.'" *Id.,* quoting *United States v. Hirani*, 824 F.3d 741, 747 (8th Cir. 2016); *accord United States v. Starks*, 157 F.3d 833, 839 n.8 (11th Cir. 1998) (recognizing that the "furtive methods" by which remuneration had been paid were sufficient evidence "from which the jury could reasonably have inferred" that defendants acted willfully).

2. Remuneration.

This Court also recognized that remuneration "is virtually anything of value." Doc. 722 at 7, quoting *Shoemaker v. Cardiovascular Sys., Inc.*, 300 F. Supp. 3d 1046, 1049 (D. Minn. 2018) (internal quotation marks omitted). Remuneration includes "the transfer of anything of value for less than its fair market value." *Id.,* citing *Bingham v. HCA, Inc.*, 783

F. App'x 868, 873 (11th Cir. 2019); *Miller v. Abbott Labs.*, 648 F. App'x 555, 561 (6th Cir. 2016).

Remuneration is broadly construed, and is intended to include "anything of value." *Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622, 678 (N.D. Ill. 2006); *United States v. Shaw*, 106 F. Supp. 2d 103, 114 (D. Mass. 2000). Under the AKS, Plaintiffs do not have to show that any payments involved in the scheme lacked fair market value. *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 29–30 (1st Cir. 1989) ("The trial court did not err in not specifically instructing the jury that the government had to prove that the payments received were not reasonable for the actual work done. The gravamen of Medicare Fraud is inducement.").

3. Inducement

This Court has concluded that "that the weight of persuasive authority reflects that Plaintiffs need only prove that *one* of the purposes of the remuneration Defendants offered or paid was to induce Medicare purchases." Doc. 722 at 17.[15] Indeed, at least five federal appellate courts have held that an AKS violation exists if *one* purpose of the remuneration was to induce Medicare purchases, even if other legitimate purposes for the remuneration existed. *See, e.g., United States v. Borrasi,* 639 F.3d 774, 782 (7th Cir. 2011) (collecting cases from the Third, Fifth, Ninth, and Tenth Circuits). In *Borrasi*, the Seventh Circuit

[15] The Court also correctly observed that "The AKS's plain language thus makes it unlawful for a defendant to pay a kickback with the intent to induce a referral, whether or not a particular referral results." Doc. 722 at 16-17, quoting *United States ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp. 2d 654, 665 (S.D. Tex. 2013).

rejected the defendant's argument that inducement must be "the primary motivation behind the remuneration" because nothing in the text of the AKS supports such a requirement. *Id.* at 781-82. No federal appellate court has held otherwise, and since the Court's summary judgment opinion, another appellate court has joined the ranks of appellate courts to hold that the one purpose test, rather than a primary motivation standard, is the correct element of proof. *United States ex rel. Lutz v. Mallory*, 988 F.3d 730, 741 (4th Cir. 2021).

C. FCA Damages and Penalties.

The FCA provides for treble damages and a civil penalty of $5,000 to $10,000 for each false claim submitted, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461. 31 U.S.C. § 3729(a). The court assesses the penalties and applies the treble damages multiplier. *See Cook Cnty.*, 538 U.S. at 132 ("[U]nder the FCA . . . if [the jury] finds liability, its instruction is to return a verdict for actual damages, for which the court alone then determines any multiplier, just as the court alone sets any separate penalty."). The imposition of penalties is mandatory. *See United States v. Hughes*, 585 F.2d 284, 286 (7th Cir. 1978). In addition, at the resolution of the action, the relator receives a share of the proceeds of the action, and also receives an award against Defendants "for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs." 31 U.S.C. 3730(d)(1). These issues are also not before the jury. *E.g., Rodriguez v. Texan, Inc.*, No. 01 C 1478, 2002 U.S. Dist. LEXIS 17379, at *1-2 (N.D. Ill. Sep. 13, 2002) (fee shifting for the court rather than for

the jury); *Roberts v. Accenture, Ltd. Liab. P'ship*, 707 F.3d 1011, 1017-18 (8th Cir. 2013) (relator's share only comes into play at the conclusion of the case).

The jury will deliberate on the amount of damages under the FCA, prior to the application of a multiplier or penalties. The FCA provides for the recovery of "damages which the Government sustains because of" a defendant's conduct. Doc. 722 at 29, n.7, citing 31 U.S.C. § 3729(a)(1). In an FCA case predicated on an AKS violation, the proper measure of damages is the full amount of each false claim. *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008). In reaching this holding, the Seventh Circuit explained: "The government offers a subsidy (from the patients' perspective, a form of insurance), with conditions. When the conditions are not satisfied, nothing is due. Thus the entire amount that [a defendant] received of these . . . claims must be paid back." *Id.* Neither the possibility that the United States would have paid for the care from another provider nor that a private insurer would have paid the submitted claims "allows [a defendant] to keep money obtained from the Treasury by false pretenses, or avoid the penalty for deceit." *Id.* The Seventh Circuit found it irrelevant to an FCA/AKS case whether Medicare patients actually received care: "Nor do we think it important that most of the patients for which claims were submitted received some medical care-perhaps all the care reflected in the claim forms." *Id.* at 453.

Rogan involved allegations that a doctor accepted kickbacks in exchange for federal program referrals. *Id.* at 451-52. Courts in subsequent FCA/AKS cases have relied favorably on this holding in *Rogan*. Just last month, another district court adopted the *Rogan* standard. *United States v. Teva Pharmaceuticals USA, Inc.*, CV No. 20-11548-

NMG, 2022 U.S. Dist. LEXIS 185301, at *9-10 (D. Mass. Oct. 11, 2022). The court noted that that while the First Circuit had not yet adopted the approach, several circuit courts already have. *Id.* *See also, e.g.*, *United States ex rel. Health Dimensions Rehab., Inc. v. RehabCare Group, Inc.*, No. 4:12CV00848 AGF, 2013 U.S. Dist. LEXIS 135498, at *10 (E.D. Mo. Sep. 23, 2013) ("the proper measure of damages is the full amount of each tainted claim"); *United States ex rel. Freedman v. Suarez-Hojos*, No. 8:04-cv-933-T-24 EAJ, 2012 U.S. Dist. LEXIS, at *12-14 (M.D. Fla. Sept. 21, 2012) ("[T]he amount of the Government's damages resulting from the payment of false claims tainted by a kickback arrangement equals the full amount that Medicare paid on such claims.").

This same approach to damages has been followed in numerous other analogous circumstances: if the government would not have paid anything for claims rendered false by the AKS violation alleged, damages are calculated as the total value of the claim. *See, e.g.*, *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 386 (4th Cir. 2015).[16] In *Tuomey*, a jury concluded that the defendants submitted claims that were false because they were tainted by referrals that violated the Stark Act. *Id.* at 371. The jury awarded the government the "sum total of all claims the government paid," and on appeal the defendants

[16] *See also United States. ex rel. Feldman v. van Gorp*, 697 F.3d 78, 88-90 (2d Cir. 2012) (calculating damages as the full amount of the grant payments made where the government paid for a program that was "not at all as specified"); *United States ex rel. Longhi v. Lithium Power Techs.*, *Inc.,* 575 F.3d 458, 473 (5th Cir. 2009) ("[W]here there is no tangible benefit to the government and the intangible benefit is impossible to calculate, it is appropriate to value damages in the amount the government actually paid to the Defendants."); *United States v. Mackby,* 339 F.3d 1013, 1018–19 (9th Cir. 2003) ("Had Mackby been truthful, the government would have known that he was entitled to nothing.").

challenged that determination. *Id.* at 386. The Fourth Circuit, relying on *Rogan*, affirmed the damages award. *Id.* The Court reasoned that the Stark Law prohibited "the government from paying *any* amount of money for claims submitted in violation of the law." *Id.* Compliance with the Stark Law was "a condition precedent to reimbursement of claims submitted to Medicare." *Id.* Therefore, the Court concluded that the government owed the defendants nothing when they failed to satisfy that condition. *Id.* Because payment of a claim by the Medicare program is conditioned upon compliance with the AKS, just as payment is also conditioned upon compliance with the Stark Act, the approach adopted by the Fourth Circuit in *Tuomey* should be followed here. *See also United States v. Novak*, No. 17 C 4887, 2018 U.S. Dist. LEXIS 150234, at *13 (N.D. Ill. Sep. 4, 2018) ("a fraud that conceals an individual's ineligibility to receive government spending intended for the benefit of third parties entitles the government to the full amount of the falsely-obtained payments").

The legislative purpose behind the AKS further supports this approach. One purpose of the AKS is to "protect patients from doctors whose medical judgments might be clouded by improper financial considerations." *United States v. Patel*, 778 F.3d 607, 612 (7th Cir. 2015). When medical judgment is so clouded, the Medicare program can no longer rely on the doctor's judgment that the item or service was reasonable or necessary, and thus does not pay for any service tainted by a kickback.

Specific to this matter, this means that both the facility fee claims and the professional fee claims for cataract surgeries implanting PL-distributed lenses are recoverable as damages. As discussed above, in every case involving providers accepting

kickbacks, courts have held that the false claims are recoverable in their entirety. In *Hutcheson*, for example, the First Circuit rejected defendants' attempt to avoid liability for the professional fees: "Nor does the fact that the physician claims sought payment for services rather than devices somehow render the fact that the physicians accepted kickbacks irrelevant." 647 F.3d at 394. The fact that Medicare elects to divide claims into facility fees and professional fees does not render either of them payable. *Id.* at 394-395 ("Blackstone's argument that Medicare would excuse these violations because of a bureaucratic mechanism or because of an implicit medical necessity requirement impermissibly cabins what the government may consider material."). Likewise, in *Cairns*, the district court held, "[t]he professional services for which MWS sought reimbursement in this case were to implant the very devices for which Fonn allegedly accepted kickbacks." *United States ex rel. Cairns v. D.S. Med. LLC*, No. 1:12CV00004 AGF, 2015 U.S. Dist. LEXIS 16533, at *13-14 (E.D. Mo. Feb. 11, 2015).

Plaintiffs limit their damages request to claims occurring within a year of an illegal incentive. Plaintiffs have conservatively employed this time frame to create reasonable, quantifiable limits to the calculation of damages, although such a limitation is not required by the AKS. Rather, each and every claim originally obtained by fraudulent means is considered false. *See* S. Rep. No. 99-345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274 (Emphasizing that each and every unlawfully submitted claim is a false claim). Both the FCA and the AKS' provisions are employed broadly to ensure that the Government is made whole. *Cook Cnty.,* 538 U.S. at 133-34 (1986 Amendments "increased

the Government's measure of recovery" and "strengthen[ed] the Government's hand in fighting false claims").

In this case, a year time frame is conservative because the kickbacks are intended to influence the claims for much longer. PL's former Vice-President of Sales testified that once physicians start using a particular lens, they tend to stick with that lens choice for a long time. When asked if there was a way to put a meaningful end date on a time period after which a physician who started using a product would no longer continue to use it, he indicated that it would be difficult to do that. When PL succeeded in converting doctors to a lens distributed by PL, it viewed those to be long-term conversions.

The one- year time horizon also fits the facts of this case because Defendants conducted many parts of their business in one-year windows. They compared their customers' utilization and ordering from one year to the next. They took physicians on annual trips, Defendants also gave annual cash donations to support customers' causes, such as conferences and cocktail party fund raisers. PL also paid bonuses to its sales representatives based on their annual sales.

In short, Defendants used a decade-long fraudulent kickback scheme to get millions of dollars of business, funded mostly by Medicare. They paid those kickbacks to the providers Medicare trusts to be conflict-free gatekeepers of medical care. Defendants propose no authority that would allow the Court to find that this illegal influence expires within a year. To the contrary, there is much authority for the proposition that the United States loses the benefit of its bargain with providers when that provider is no longer conflict-free.

Defendants may argue that the Eighth Circuit's opinion in *Cairns* alters this analysis, but the Eighth Circuit's decision was limited by its terms to interpretation of "resulting from" in the AKS 2010 amendment, and said nothing about FCA damages. Nor did it overrule the *Rogan* damages framework. Consistent with every court to address the damages framework in an FCA/AKS matter, the full amount paid for any false claim submitted to Medicare is recoverable as damages.

VI. Unresolved Issues.

The parties have raised most of their disputed and unresolved issues in pre-trial submissions. Many of these, including multiple liminal motions and the jury instructions, address the impact of the Eighth Circuit's decision in *Cairns* to this matter. Plaintiffs have addressed their approach to FCA liability in this Trial Brief, and will further address Defendants' arguments in response to the liminal motions and in the position statements contained in the proposed joint jury instructions.

A couple procedural issues remain:

- There are individuals on both parties' witness lists who were not deposed in this matter. The parties agreed to a limit of a certain number of hours of deposition per side, which allowed each party to obtain the information required to proceed but did not enable them to depose every potential trial witness. Plaintiffs seek an instruction that if either side calls a witness who was not deposed in this matter, the other side will be afforded an opportunity to formally question that witness (*e.g.*, by trial deposition) in advance of the witness' testimony.

- Both parties intend to present certain witnesses by deposition designation, as set forth in the Court's Trial Notice. The parties have agreed that any witness who will not testify live may be presented via designation, while any witness who will testify live may not be presented via designation. (This agreement does not limit the use of 30(b)(6) witnesses). It is possible that Plaintiffs would not present deposition testimony of a witness based on Defendants' intention to call that witness, but Defendants would then elect not to call that witness. Plaintiffs seek clarification that they would in that instance be permitted to introduce evidence from that witness and have it be considered to be part of Plaintiffs' case-in-chief.

Dated: November 23, 2022

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was sent via the Court's electronic filing system to all counsel of record on November 23, 2022.

/s/ Chad A. Blumenfield
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